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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/699,098

10/30/2003

Florenziano Della Torre

P/4659-2

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

09/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/699,098	TORRE, FLORENZIANO DELLA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 July 2007 has been entered.

### ***Claim Objections***

2. Claims 8-12 are objected to because of the following informalities: The claims are improperly identified as "currently amended." The claims are new, since the after final amendment filed 18 May 2007 introducing claims 8-12 was not entered. Appropriate correction is required.

### ***Election/Restrictions***

3. Newly submitted claims 11-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 11-12 set forth a method for blood treatment, while the originally filed claims are drawn only to an apparatus for blood treatment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claims 11-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,561,997 to Weitzel et al in view of US 4,828,543 to Weiss et al.

In the specification and figures, Weitzel discloses the device substantially as claimed by applicant. With regard to claim 8, Weitzel discloses a hemofiltration or dialysis system that acts as a renal assist device (see column 2, lines 15-20). The apparatus comprises a hemofiltration system 300 with a blood path or connecting means 58/72 that connects to pass blood to and from a patient 100, pump or blood processing means 52, a container 60 and pump 56 for infusing anticoagulant (corresponding to applicant's means for adding drugs), containers 62, 64, pump 56 for replacement fluid (corresponding to applicant's means for feeding refill liquid), and blood filter 48 (see FIG 1, column 4, line 40 to column 5, lines 20).

Weitzel fails to disclose an oxygenating device connected upstream of the blood filter. However, Weiss discloses an extracorporeal treatment device that uses mass

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transfer devices such as filters and oxygenators to withdraw, treat, and return blood to the patient. In particular, the device seeks to circulate, cleanse, and oxygenate a patient's blood in the event of blood system failure (see column 1, line 63 to column 2, line 11). The apparatus includes a blood path (see line 102 in FIG 9), pumps 104, 106, and treatment means connected in series (142A, 142B, 142C). The treatment means may comprise blood filters or a blood oxygenator (see column 25, line 35 to column 26, line 52, column 32, lines 12-14). The treatment means connected in series (wherein the oxygenator may be located upstream of the filter) allow for a combination of a plurality of treatments that replace a patient's damaged blood system (see column 26, lines 37-52, column 1, line 63 to column 2 line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an oxygenator upstream of the filter as disclosed by Weiss in the apparatus disclosed by Weitzel in order to provide a plurality of treatments to replace the function of a patient's damaged blood system, as taught by Weiss.

With regard to applicant's claim drawn to the operation of the pump, applicant claims the operation of the blood pump to create a particular flow rate. Such a limitation is considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Weitzel specifically discloses that the blood pump 52 may be set to pump blood at a rate of 10mL/min up to 1000 mL/min (see column 7, lines 34-67). Weitzel's disclosure

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of possible pump rates indicate that the pump 52 is capable of performing at the rate claimed by applicant, meeting the limitations of the claims.

With regard to claim 9, Weitzel illustrates a single blood pump (see FIG 1) for pumping blood from and to the patient.

With regard to claim 10, Weitzel fails to disclose an oxygen tank and an outlet connected to an oxygenator. Weiss discloses an extracorporeal blood treatment system with a blood inlet 134, outlet 136, and membrane oxygenator with an O<sub>2</sub> tank 276 as the oxygen supply and a CO<sub>2</sub> outlet 150 in order to drain spent oxygen and CO<sub>2</sub> from the oxygenator (see FIG 8, column 25, line 60 to column 26 line 68). Therefore, it would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an oxygenator with the associated oxygen supply and venting components disclosed by Weiss in the apparatus disclosed by Weitzel in order to provide a plurality of treatments to replace the function of a patient's damaged blood system and to provide a means for venting CO<sub>2</sub> and unused O<sub>2</sub>, as taught by Weiss.

### ***Response to Arguments***

6. Applicant's amendment and arguments filed 18 July 2007 have been entered and considered, but applicant's arguments are not persuasive.

7. Applicant argues that the instantly claimed blood flow rate is not an obvious variation from the prior art. However, Weitzel discloses that the apparatus is capable of pumping between 10mL/min and 1000mL/min. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of

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obviousness exists. See MPEP 2144.05(I). It is the position of the Examiner that the disclosure by Weitzel provides a broad range of flow rates from which an operator is free to choose, depending on the components employed in the device. Since Weitzel discloses a broad range and applicant's range falls completely within the range disclosed by Weitzel, the claimed ranges are not patentable over the prior art.

8. Applicant further argues that the present invention comprises only a single blood pump. Weitzel, too, discloses a single blood pump.

9. Applicant also argues that in the instant invention the oxygenator acts directly on the blood. Applicant illustrates that oxygen is fed through a membrane oxygenator 71. Weiss discloses a similar setup, with oxygen being fed to a membrane filter device via conduit 152 to act on the blood.

10. Accordingly, applicant's invention fails to distinguish from the prior art.

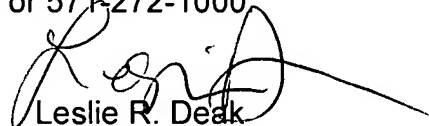
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
30 August 2007